K003775

JAN 12 2001

510(k) Summary
Portable Breast Compression Device

Common/Classification Name: Accessory to Scintillation Camera, 21 CFR 892.1110

PEM Technologies, Inc.
5611 Roosevelt Street
Bethesda, MD 20817-6739

Telephone: 301-564-0835
FAX: 301-564-5386

Contact: Dr. Irving Weinberg
Prepared: November 30, 2000

A. LEGALLY MARKETED PREDICATE DEVICES

The **Portable Breast Compression Device** is an accessory to an imaging device, so it carries the classification of the imaging device. The imaging device in this case is the scintillation (gamma) camera, a Class I (reserved or non-exempt) device. A number of compression devices have been cleared for use with x-ray and other imaging modalities, so in regard to the interaction with the patient, the device is also substantially equivalent to the Bennett X-Ray Technologies Motorized Compression/Breast Thickness Indicator, a part of the Contour Mammography System M-CTR (K925725). Other similar compression devices include the Lorad Corporation's M-IIE (K934748) and Fischer Imaging Corporation's compression component of the Mammotest Mammography System (K861692).

B. DEVICE DESCRIPTION

The portable breast compression device for scintillation (gamma) cameras is intended for medical purposes to apply controlled compression to the patient's breast during scintimammography procedures. The device includes three major components: a pair of paddles, a slide base that holds the paddles, and a roll-around stand that supports the sliding base.

The device is primarily intended for use with patient radiologic support tables that support a patient in the prone position while allowing the breast to be pendulant through a table cutout. The portable device is designed to accommodate different table heights so that it can be

positioned beneath the table. The paddles hold and immobilize the breast by the application of compression.

One paddle is held in a fixed position on the slide base, and the other paddle slides forward and backward on the slide base. The slide base provides the mechanism that allows the moveable paddle to slide back and forth. Initial compression is applied via an electrical stepping motor mounted on the slide base. Manual fine-adjustment control knobs are mounted on the slide base that can reduce or increase compression force.

The roll-around stand provides manual height adjustment and also includes a locking pivot that allows the slide base and paddles to swivel from the vertical to the horizontal position, as well as intermediate positions.

C. INDICATIONS FOR USE

The portable breast compression device is intended for medical purposes to support, position, immobilize, and apply controlled compression to a patient's breast during a scintigraphic imaging (scintimammography) procedure.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

As an accessory, the **Portable Breast Compression Device** has slightly different indications for use from the device for which it is an accessory, the scintilation (gamma) camera. The indications for use are also slightly different from the legally marketed predicate compression devices, since these are indicated for use with other imaging modalities. However, the intended use with respect to the patient is clearly the same. The **Portable Breast Compression Device** has the same technological characteristics as the predicate devices. Where descriptive characteristics may be insufficient to ensure substantial equivalence, performance testing was carried out. This premarket notification has described the characteristics of the **Portable Breast Compression Device** in sufficient detail to assure substantial equivalence, except for the few characteristics that require performance testing, and in the latter case, performance testing demonstrates substantial equivalence.

This pre-market submission has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

E. TECHNOLOGICAL CHARACTERISTICS

The new device and the predicate devices all apply controlled compression to the patient's breast in order to position, support, and immobilize the breast during imaging procedures. For all of these devices, compression is provided between two paddles of polymeric materials, using electromechanical means and incorporating appropriate compression-limiting features.

F. TESTING

Testing to UL-2601 and EN-60601-1-2 will be successfully completed prior to marketing of the device.

G. CONCLUSIONS

In summary, this pre-market submission has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 12 2001

Mr. T. Whit Athey, Ph.D.
PEM Technologies Inc.
c/o C.L. McIntosh & Associates
12300 Twinbrook Parkway, Suite 625
ROCKVILLE MD 20852

Re: K003775
Portable Breast Compression Device for
Scintillation (Gamma) Cameras
Dated: December 06, 2000
Received: December 06, 2000
Regulatory Class: I
21 CFR §892.1100/Procode: 90 IYX

Dear Dr. Athey:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K003775

Device Name: Portable Breast Compression Device for Scintillation (Gamma) Cameras

Indications for Use:

The portable breast compression device is intended for medical purposes to support, position, immobilize, and apply controlled compression to a patient's breast during a scintigraphic imaging (scintimammography) procedure.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003775

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)